

**REMARKS**

Reconsideration of this application is respectfully requested.

**A. Status of the Claims**

Prior to this amendment, claims 15-18 and 20-26<sup>1</sup> were pending. In the above amendment, claims 15, 17 and 18 have been amended. Claim 16 has been canceled. No new matter is introduced by amendment.

Upon entry of the amendment, claims 15, 17, 18 and 20-26 will be pending and under consideration. Applicant reserves the right to prosecute any subject matter related to the non-elected and/or cancelled claims in future continuation or divisional applications.

**B. Double Patenting**

Claims 15-18 and 20-26 stand provisionally rejected for obviousness-type double patenting over Application No. 10/595,045. A Notice of Missing Requirements was mailed in the '045 application on February 2, 2007. The final deadline to respond to that Notice, with a five month extension of time, was September 2, 2007. Applicant did not file a response by that deadline, as is reflected in the electronic file wrapper on PAIR. Accordingly, the '045 application is abandoned. Therefore, this rejection should be withdrawn.

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<sup>1</sup> The Office Action indicated that claims 15-26 are pending and rejected. However, claim 19 was previously canceled, as reflected in the listing of claims filed with the last response.

**C. Claim Rejections - 35 USC § 112, Second Paragraph**

Applicant thanks the Examiner for acknowledging that the rejection under 35 U.S.C. § 112, second paragraph, has been withdrawn.

**D. Claim Rejections - 35 USC § 103(a)**

Claims 15-18 and 20-26 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Johnson (U.S. Patent No. 6,611,833) in view of Friend (US Patent No. 6,801,856). (Office Action at pages 4-9.) Applicant respectfully traverses the rejection.

As amended, claim 15 recites:

A method of characterising a treatment applied to a population of cells, comprising:

providing a treatment to a population of cells;

deriving a plurality of cellular features from at least a first captured image of the population of cells that have been exposed to the treatment;

creating an on-target effect signature, which is characteristic of an on-target effect of the treatment on the population of cells, from a group of cellular features selected from the plurality of cellular features derived from the population of cells, the group of cellular features relating to cellular properties involved in the on-target effect;

creating a side effect signature, which is characteristic of a side effect to the on-target effect, from a second group of cellular features selected from the plurality of cellular features derived from the population of cells, the second group of cellular features relating to cellular properties not being involved in the on-target effect;

creating an on-target effect metric derived from the on-target effect signature;

creating a side effect metric derived from the side effect signature; and

comparing the on-target effect metric to the side effect metric to thereby characterise the response of the population of cells to the treatment.

In the recited method, an on-target effect signature and a side effect signature are created from a (first) group of cellular features and a second group of cellular features. Those groups of cellular features are selected from a single plurality of cellular features derived from a first captured image of a population of cells. Thus, the first and second groups of cellular features, used to generate the on-target and side effect signatures, respectively, are obtained from the same cells. In that way, the method allows for measurement and characterization of the on-target effect and side effect of a treatment that occur simultaneously on a single population of cells as a result of a treatment.

In contrast, Johnson describes a method of creating a database of tissue parameters from normal and abnormal tissues. Johnson then compares a user supplied tissue sample to the database and characterizes the tissue as either normal or abnormal. The method of Johnson allows for identification of normal elements of tissues that do not appear otherwise normal. (Johnson at col. 5, lines 27-52.) In the methods of Johnson features of a tissue sample are compared to a set of features of known tissues in a database and a comparison is made between the degree of presence or other characteristic of the features in the tissue and in tissues in the database.

Johnson does not teach a method comprising “creating an on-target effect signature, which is characteristic of an on-target effect of the treatment on the population of cells, from a group of cellular features selected from the plurality of cellular features derived from the population of cells, the group of cellular features relating to cellular properties involved in the on-target effect” and also “creating a side effect signature, which is characteristic of a side effect to the on-target effect, from a second group of cellular features selected from the plurality of cellular features derived from the population of cells, the second group of cellular features relating to cellular properties not being involved in the on-target effect.” In particular, Johnson nowhere teaches or fairly suggests characterizing first and second groups of cellular features selected from a single plurality of cellular features derived from a population of cells, as claimed. Johnson also, therefore, necessarily fails to disclose a method comprising “comparing the on-target effect metric to the side effect metric,” in which both of those metrics are obtained from first and second groups of cellular features selected from a single plurality of cellular features derived from a population of cells. For all of those reasons Johnson fails to teach or fairly suggest the claimed invention.

Friend does not remedy the deficiencies of Johnson. The Examiner characterizes Friend as “applying a treatment to cells to measure effectiveness (on target effect) and toxicity (side effect) on cellular constituents.” However, Friend does not teach a method comprising “creating an on-target effect signature, which is characteristic of an on-target effect of the treatment on the population of cells, from a group of cellular features selected from the plurality of cellular features derived from the

population of cells, the group of cellular features relating to cellular properties involved in the on-target effect" and also "creating a side effect signature, which is characteristic of a side effect to the on-target effect, from a second group of cellular features selected from the plurality of cellular features derived from the population of cells, the second group of cellular features relating to cellular properties not being involved in the on-target effect." In particular, Friend nowhere teaches or fairly suggests characterizing first and second groups of cellular features selected from a single plurality of cellular features derived from a population of cells, as claimed. Friend also, therefore, necessarily fails to disclose a method comprising "comparing the on-target effect metric to the side effect metric," in which both of those metrics are obtained from first and second groups of cellular features selected from a single plurality of cellular features derived from a population of cells. For all of those reasons Friend, like Johnson, fails to teach or fairly suggest the claimed invention.

Nothing in Johnson or Friend suggests modifying or combining the teachings of the references to arrive at the claimed invention. In fact, if anything the two references taken together lead the skilled artisan away from the claimed invention because both references teach making a simple comparison of profiles of tissue characteristics to known tissue profiles in order to identify similarities between tissues. In contrast, the claims do not rely on such comparisons, but instead provide a method to characterize multiple features present in a single image of cells following a treatment. Accordingly, the claimed methods are non-obvious over the cited art and the rejection for obviousness should be withdrawn.

**E. Conclusion**

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing the pending claims in condition for allowance.

Applicants submit that the proposed amendments of the claims do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Please grant any extensions of time required to enter this paper and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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